Maryland Board of Pharmacy
Public Board Meeting

Agenda
August 21, 2019

Name	Title	Present	Absent
Ashby, D.	Commissioner		
Bouyoukas, E	Commissioner		
Evans, K.	Commissioner		
Hardesty, J.	Commissioner/Treasurer		
Laws Jr, A.	Commissioner		
Leikach, N.	Commissioner		
Morgan, K.	Commissioner/President		
Oliver, B	Commissioner		
Rusinko, K.	Commissioner		
Toney, R.	Commissioner/Secretary		
Yankellow, E.	Commissioner		
Bethman, L.	Board Counsel		
Felter, B.	Board Counsel		
Speights-Napata, D.	Executive Director		
Fields, E.	Deputy Director /Operations		
James, D.	Licensing Manager		
Leak, T.	Compliance Director		
Clark, B.	Legislative Liaison		
Chew, C.	Management Associate		

<table>
<tr><th>Subject</th><th>Responsible Party</th><th>Discussion</th><th>Action Due Date (Assigned To)</th></tr>
<tr><td>I. Executive Committee Report(s)</td><td>A.) J. Hardesty, Treasurer

B.) R. Toney, Secretary</td><td>Members of the Board with a conflict of interest relating to any item on the agenda are advised to notify the Board at this time or when the issue is addressed in the agenda.

1. Call to Order

2. Sign-in Introduction and of meeting attendees – (Please indicate on sign-in sheet if you are requesting CE Units for attendance)

3. Distribution of Agenda and packet materials

4. Review and approve May 2019 Public Meeting Minutes and July 2019 Public Meeting Minutes</td><td></td></tr>
<tr><td>II. A. Executive Director Report</td><td>D. Speights-Napata, Executive Director</td><td>1. Staffing Update

2. Staff Training/Certification Updates

3. Upcoming Holiday Closure</td><td></td></tr>
<tr><td>B. Operations</td><td>E. Fields, Deputy Director/ Operations</td><td>1. Procurement and Budget Updates
a: July 2019 Financial Statements

2. Management Information Systems (MIS) Unit Updates
a: None</td><td></td></tr>
<tr><td>C. Licensing</td><td>E. Bouyoukas, Commissioner</td><td>1. Unit Updates

2. Monthly Statistics
<table><tr><th>License Type</th><th>New</th><th>Renewed</th><th>Reinstated</th><th>Total</th></tr><tr><td>Distributor</td><td>15</td><td>70</td><td>0</td><td>1,334</td></tr></table></td><td></td></tr>
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			Pharmacy	**22**	**0**	**0**	**2,056**
			Pharmacist	**99**	**497**	**0**	**12,194**
			Vaccination	**35**	**90**	**0**	**4,717**
			Pharmacy Intern - Graduate	**4**	**0**	**0**	**47**
			Pharmacy Intern - Student	**29**	**3**	**0**	**822**
			Pharmacy Technician	**125**	**338**	**3**	**9,910**
			Pharmacy Technician-Student	**0**	**0**	**0**	**30**
			TOTAL	**334**	**998**	**3**	**31,194**
D. Compliance	**T. Leak, Compliance Director**	**1. Unit Updates** **2. Monthly Statistics** **Complaints & Investigations:** New Complaints - 32 • Professional Misconduct – 2 • Medication Error – 1 • Refusal to Fill - 3 • Applicant – 2 • Child Support – 2					

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		• Customer Service – 2 • Disciplinary Action in Another State – 2 • Dispensing Error – 1 • Employee Pilferage – 4 • Facility Issues – 1 • Fraudulent Prescriptions – 2 • Inspection Issues - 9 Resolved (Including Carryover) – 48 Actions within Goal – 38/48 Final disciplinary actions taken – 11 Summary Actions Taken – 0 Average days to complete – 0 **Inspections:** Total - 127 Annual Inspections - 115 Opening Inspections - 6 Closing Inspections - 2 Relocation/Change of Ownership Inspections - 2 Board Special Investigation Inspections – 2	
E. Legislation & Regulations		**Regulations** None **Legislation** None	

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III. Committee Reports **A. Practice Committee**	**Evans, K. Commissioner**	**Nancy Fingerhut:** As you may be aware, there is significant regulatory movement in the compounding industry. United States Pharmacopoeia (USP) published revised chapters on nonsterile compounding <795> and sterile compounding <797>. In addition, FDA continues to make efforts to finalize the Memorandum of Understand (MOU) for state Boards of Pharmacy to sign, regarding interstate distribution of compounded medications. In light of these changes, our pharmacy would like clarification on both topics: 1. Will the Board enforce the new 2019 USP <795> and <797> chapters, effective December 1, 2019, or maintain the adopted standard of the current 2015 version? 2. If Board review and adoption of USP 2019 chapters is required, is there a timeline for when this will occur? Does the Board anticipate adopting in full or in part, if at all? 3. Is the Board positioning to sign the current draft of the MOU? As a licensee governed by the Board, our legal and compliance team is seeking to ensure we understand the regulatory path ahead. Your clarification and insight is most appreciated and helpful as we come to terms with these changes. **Proposed Response:** 1) Yes, the Board will be enforcing USP-797, as amended, when the amendments become effective. 2) The Board plans to begin inspecting for the new standards when they become effective; however, the Board may take into consideration reasonable implementation timelines for certain gaps that are identified.	

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		3) The Board has reviewed prior drafts of the MOU, but has not recently engaged with NABP on this issue. **Raymond Lake:** Scheduling of Gabapentin 1. Do you know if the MD BOP is considering making gabapentin a C-V? 2. Will we need to treat it as a C-V in a year since it originates as a C-V from our VA based wholesaler? **Proposed Response:** 1) The Board of Pharmacy is not responsible for scheduling drugs. For further information on this issue, please contact the office of the Secretary of Health at 410-767-6500 or online at https://health.maryland.gov/Pages/contactus.aspx . 2) No. Though your Virginia-based wholesaler will need to abide by its home-state laws, as a Maryland practitioner or business doing business in Maryland with Maryland patients, you will be subject to Maryland laws and regulations. **Ronald Keech:** When will the Maryland Board of Pharmacy decide if it will adopt and enforce USP 800? The owner of the store does not want to do construction if it is not going to be enforced. Can you let me know if it will be enforced or not? The time is running out for us to build before the December 1 deadline. Also, we want to give our patients at least a month notice to find a pharmacy that is USP 800 compliant if it will be enforced.	

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		Proposed Response: The Board is not currently enforcing USP-800 specifically; however, please be advised that provisions that overlap with USP-797 will be enforced. **Farzana Musawwir:** I work at a heart failure clinic under UMMC, Currently this clinic has a non-regulatory status. Advance heart failure patients are seen in this clinic and have infusion at times, based on need. Often time's patient needs to go home with a few doses of oral K supplement, or diuretic supply based on weekend or situation. Clinic has a small inventory of medications of such urgent need. I would like to have some clarification on what we can do as pharmacists in this clinic. Questions are: 1. Are we able to manage the inventory of these medications 2. Are Pharmacist or Pharmacy technicians under supervision of RPh eligible to dispense medications from this inventory for patient to take home? If yes, which are the criteria? If not, who can dispense and under chich criteria? **Proposed Response:** 1) Generally, yes. 2) No. Pharmacists may not dispense outside of a licensed pharmacy; however, a pharmacist may apply to dispense from a clinic under a drug therapy management contract, pursuant to COMAR 10.34.31. **Wendy Crump:** I am writing to you on behalf of Merck and Sanofi Pasteur. We are currently finalizing arrangements to distribute a new pediatric vaccine, VAXELIS, into your state. VAXELIS is the first hexavalent pediatric vaccine approved in the US. The partners would like to designate Sanofi Pasteur as the entity that will handle distribution into your state and across the US, and are writing to	

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		confirm that we will be able to obtain all the necessary licensure. The facts of the arrangement are specified below. 1. MCM, an unincorporated unpopulated Pennsylvania partnership, holds the BLA for VAXELIS. 2. Sanofi Pasteur owns 50% of MCM, with Merck holding the other 50%. 3. Sanofi Pasteur is considered an affiliate of MCM and a manufacturer of VAXELIS under 21 U.S. Code § 360eee of the Federal Food, Drug, and Cosmetic Act. 4. Sanofi Pasteur is the contracted manufacturer of VAXELIS and produces & packages VAXELIS on behalf of MCM. 5. At all points prior to sale, an affiliate of Sanofi Pasteur (MCM) will hold title to VAXELIS. 6. Sanofi Pasteur will have physical control of VAXELIS at all points from final packaging until delivery. 7. At time of delivery, Sanofi Pasteur will have the ability to pass title of VAXELIS to the customer. 8. Sanofi Pasteur will have the authority to pass title to the customer through a consignment agreement with MCM. 9. All invoicing, payment, and delivery will be done by Sanofi Pasteur, on Sanofi Pasteur letterhead. 10. Sanofi Pasteur will handle all recalls and returns. 11. At all times, Sanofi Pasteur will be jointly and severally liable for all MCM debts as per Pennsylvania Partnership Law. 12. At all times, Sanofi Pasteur will be jointly responsible for FDA reporting on VAXELIS. 13. Sanofi Pasteur has a valid state manufacturer license in PA. (Sanofi Pasteur, Inc. One Discovery Drive; Swiftwater, PA 18370 Certificate(s): 1000001086 issued: 1/1/1978 expires: 12/31/2019; 8000000069 issued: 9/1/1994 expires: 12/31/2019) 14. Sanofi Pasteur has a valid license to distribute drug product into your state as a manufacturer. Given these set of facts, we are seeking an answer to whether Sanofi	

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		Pasteur will be able to distribute VAXELIS into your state under its existing license? Sanofi Pasteur will submit such additional applications or information as you request to support the claims above and to ensure our license properly reflects that we are distributing VAXELIS. **Proposed Response:** The business that you have described would require a long-form distributor application. Under Md. Code Ann., Health Occ. § 12-6C-03(2), manufacturers may only distribute their own drugs that they hold title to. In this case, it is a 50% owned subsidiary that holds title. Therefore, the long-form application is required. **Maryland Board of Pharmacy Rehabilitation Services Program:** Committee has revised notice for Board posting to reflect COMAR regulation 10.34.10.05	
B. Licensing Committee	**D. Ashby, Chair**	**1. Review of Pharmacist Applications:** **a. #116555-** The applicant's MDBOP application expired on 4/11/2019. She is requesting the Board grant her an extension of her NAPLEX score transfer (8/2/2017) and MDBOP application. The score is valid for one year from the date of examination which expired 08/02/2018. She took the MPJE exam and passed on 7/2/2019. She has moved and had two deaths in her family. The applicant does hold an active license in DC. The Licensing Unit did inform the applicant of options. *Committee' s Recommendation: Approve 3 month extension of NAPLEX score and MDBOP application*	

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		b. **#122376-** The applicant is requesting ADA testing accommodations for the MPJE and NAPLEX exams. He has been diagnosed with ADHD and he is easily distracted. He would like a separate testing room. *Committee' s Recommendation: Approve* **c.** **#115787-** The applicant is requesting the Board approve an extension of her NABP ATT number (Authorization to Test) which is due to expire on (8/20/2019) and additional preparation time for the MPJE exam. The applicant indicated that she has been recently diagnosed with Graves' disease. She must frequently report for routine lab-work, f/u doctor appointments, ultrasounds, etc… She does not feel adequately prepared to sit for any exam prior to 8/20/2019. *Committee' s Recommendation: Approve,6-month extension of the NABP ATT number* **d.** **#117672** (Withdrawn Exam application packet on 6/18/2019) - The Board has approved two prior NAPLEX score extension request. Her NAPLEX score expired on or about 12/27/2018. Extensions were granted on 1/16/2019 until 2/28/2019 & 4/18/2019 until 6/30/2019. The applicant is requesting via email, a third NAPLEX score transfer extension. She states that she has no options available to enable her to retake the NAPLEX, as a single parent struggling with no job. *Committee' s Recommendation: Approve, 3-month extension (12/2019)* ***e.*** **#07771**- The licensee renewed his license online on 7/10/2019. The licensee is requesting a refund of his	

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		renewal fee of $261. He is aware that the Board has a non-refundable policy. *Committee' s Recommendation: Deny* ***f.*** **#12437-** The expired pharmacist is requesting the Board grant her approval to pay the renewal fee of $261, instead of being charged the reinstatement fee of $524. She states that her license expired on 6/30/2019, which was a Sunday. Her renewal application was postmarked 7/1/2019. She states that her family experienced an unexpected loss on 6/15/2019, when her mother-in-law passed away in Nigeria. She traveled to Nigeria for the funeral on 7/4/2019 and purchased her ticket on 6/29/2019. *Committee' s Recommendation: Approve* ***g.*** **#118733-**The applicant's MPJE exam extension request was reviewed by the Licensing Committee on July 3, 2019. *Committee' s Recommendation: Approve a 6-month extension* **2. Review of Pharmacy Intern Applications: NONE** **3. Review of Pharmacy Technician Applications: NONE** **4. Review of Distributor Applications:** **a. #D06504-** Company is requesting waiver of the reinstatement fee (1,500). Company's permit was issued 01/31/2019. Company was made aware permit was going to	

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		expire 05/31/2019 and required the submission of a renewal application. Renewal application was received by the Board 07/22/2019. *Committee' s Recommendation: Deny* **b. #D05163**- Company is requesting waiver of the reinstatement fee (1,500). The renewal application was received 05/09/2019 without the fee. An email was sent 05/09/2019, requesting the renewal fee. The renewal fee was received 07/29/2019. The due date of the renewal was 05/31/2019. *Committee' s Recommendation: Deny* **5. Review of Pharmacy Applications: NONE** **6. Review of Pharmacy Technicians Training Programs:** **a. NHA EXCPT Update:** New training Module (Online) Does the Board want to review updates to the programs. Full update is 2,130 pages **b. Pillbox** *Committee' s Recommendation: Deny, the program does not meet MDBOP requirements* ***c.* Greensboro Pharmacy Inc.** *Committee' s Recommendation: Approve* **7. Review of Contraception Training Programs:**	

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		a. COMAR section that outlines approval criteria 10.34.40.01-6 APHA Program Birth Control Pharmacist program Kris Rusinko and Daniel Ashby Recused *Committee' s Recommendation: Approve* **8. New Business:** a. **BS-** I have a question about reciprocating licenses. When a pharmacist that is licensed in another state reciprocates their license to Maryland, are they able to shadow another Maryland licensed pharmacist until their license is granted by The Board? I have a few candidates for hire at Trivergent Health Alliance that are in the process of reciprocating their license to Maryland. They have applied for reciprocation already and have completed all requirement with exception of passing the MJPE. (Our question is, until they are licensed, are they allowed to shadow a licensed pharmacist in order to learn our workflow and processes.) They would not be dispensing medication, providing education to patients, or any other functions of a pharmacist until they are licensed in the State of Maryland. Our HR department is looking for something in writing from The Board stating that they are able to be onsite to learn workflow so long as they are not performing any duties of a pharmacist. Could you please help us with this issue? **Board Counsel response:** Provided that a pharmacist applicant is not practicing pharmacy or engaged in any other type of patient care requiring licensure, an applicant can begin employment and	

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		orientation with a pharmacy. The Board lacks any jurisdiction to prohibit otherwise. *Committee' s Recommendation: Approve* *b.* **ES**- Requestor was requesting to open a Pharmacy Waiver. To provide immunization in businesses to churches, schools, and other venues. *Committee' s Recommendation: Board Response: Dear ES:* *The Board of Pharmacy has received your application for a waiver pharmacy permit for a business that would administer influenza and other vaccinations to its patients.* *After reviewing your inquiry and proposed business model, the Board has determined that a pharmacy permit is not required to establish the business that you have proposed. In fact, the proposed business does not meet Maryland's legal definition of a pharmacy, as it would not compound, dispense or distribute prescription or nonprescription drugs (HO 12-101(t)).* *Though the business that you have proposed does not meet the definition of a pharmacy and thus does not require a permit from the Board, the Board does not prohibit a pharmacist from establishing or working for such a business (COMAR 10.34.32.03). For further information on establishing such a business, you may wish to employ a private attorney to help you determine an appropriate business entity and navigate any legal requirements for such a business.*	

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C. Public Relations Committee	**E. Yankellow, Chair**	**Public Relations Committee Update:**	
D. Disciplinary	**J. Hardesty, Chair**	**Disciplinary Committee Update**	
E. Emergency Preparedness Task Force	**N. Leikach, Chair**	**Emergency Preparedness Task Force Update**	
IV. Other Business & FYI	**J. Hardesty, Treasurer**		
V. Adjournment	**J. Hardesty, Treasurer**		